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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,037	02/22/2000	DAVID MICHAEL HEERY	PM264015	6259

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EXAMINER
MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
1636	21

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/423,037	Applicant(s) HEERY ET AL.	
	Examiner Terry Mckelvey	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *5,6 and 14-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 7-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, LXXLL, SRC-1, oestrogen receptor species, claims 1-4 and 7-13 in Paper No. 16, filed 11/13/01 is acknowledged.

Claims 5-6 and 14-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 16.

Complete cancellation of the claims to the non-elected invention must also include amending the examined claims so that they read only upon the elected invention.

Specification

The disclosure is objected to because of the following informalities: the Brief Description of the Drawings required in the specification, is absent.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 7-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for identifying inhibitor compounds comprising "taking" a potential inhibitor compound, a liganded nuclear receptor or (specific) fragment thereof, a fragment comprising a signature motif of a nuclear protein and detecting the presence or absence of inhibition of the interaction. These method claims are genus claims because they comprise the use of different products each of which constitutes a genus: any nuclear protein signature motif, and any liganded nuclear receptor or fragment thereof which interacts with the signature motif, from any species and from any allele within a species. Thus, the claimed methods encompass the use of

proteins (the nuclear signature motif and the liganded nuclear receptor or fragment) which are either not described at all in the specification (for the nuclear protein signature motif from proteins other than those listed, or for nuclear receptor or fragments thereof not listed) or are only described for a specific allele and species and thus not described for other alleles and species. These other proteins encompassed by the claims for use in the claimed method have one or more amino acid substitutions, deletions, insertions, and/or additions compared to the particular proteins referred to within the specification.

Except for a single example of the signature motif, LXXLL, the specification and claims do not indicate what distinguishing structural attributes are shared by the products used by the members of the genus. The distinguishing structural characteristics taught for the nuclear receptor are either incomplete or not sufficiently distinguishing from other structures that do not have the claimed interaction ability. No other signature motifs are taught except for a version of LXXLL which has an additional amino acid limitation. The specification and claims do not place any limit on the number of amino acid substitutions, deletions, insertions, and/or additions that may be made to the proteins used in the claimed methods. Thus, the scope of the claims includes numerous

structural variants of the products used in the methods, and the genus is highly variant because a significant number of structural differences between the products used by the genus members is permitted. Although these types of changes are routinely done in the art, the specification and claims do not provide any description as to what changes can or should be made. Structural features that could distinguish compounds used in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify members of the products used in the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common structural attributes or characteristics that identify the products used by the members of the genus, and because the products used by the members of the genus are highly variant, the specific nuclear receptors and nuclear proteins (especially in the absence of the description of the fragments used in the claimed method) referred to in the specification are insufficient to describe the products used in the genus, and thus the method using the products are not described. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species methods to

describe the genus. Thus, applicant was not in possession of the claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 7-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, etc, the use of (the extended preamble beginning with "between:" and ending with "target genes;") renders the claims vague and indefinite because it is unclear how the intended use "for identifying ..." with the different limitations modifies the actual method steps which comprise only a small portion of the total claim. Amending the claim to remove the structural and other important limitations from the preamble and placing them in the actual method steps would be remedial.

Regarding claim 1, etc, the use of "method comprises taking:" renders the claims vague and indefinite because "taking" in this context is unclear. Does it mean "placing in

contact"? If so, how is that "taking"? Amending the claim to positively recite what specific steps make up the method would be remedial.

Regarding claim 1, etc, there is no positive antecedent basis for "the potential inhibitor compound" because the preamble states "inhibitor compounds".

Regarding claim 1, etc, the use of "defined in this claim in b) above" renders the claims vague and indefinite because it is attempting to define a claim based upon the claim itself, essentially circular reasoning. Amending the claim to delete "defined in this claim in b) above" would be remedial since there is positive antecedent basis for "the second region" by itself.

Regarding claim 7, etc, the use of "any one of claims 1, 2 and 5" renders the claims vague and indefinite because it is unclear whether either 1 or 2 and 5 is being claimed, or one selected from the group consisting of 1, 2 and 5 is being claimed. Using alternative language, such as "A method according to claim 1, 2, or 5" would be remedial.

Regarding claim 12, the use of "wherein the method is in the form of a 2-hybrid assay system" renders the claim vague and indefinite because without a positive recitation of how the method steps in the base claims are individually further

limited, the metes and bounds of the claim are unclear. Amending the claim to recite an independent claim reciting the specific method steps would be remedial.

Regarding claim 13, the use of "wherein the potential inhibitor is in the form of a peptide library" renders the claim vague and indefinite because there is no positive antecedent basis for "the potential inhibitor" because "the potential inhibitor compound" is what is recited and it is unclear how a single potential inhibitor compound can be in the form of a peptide library which implies more than one compound.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2)

voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4 and 7-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Chambon et al (U.S. Patent No. 6,268,173 B1).

Chambon et al teach a screening method for identifying a nuclear receptor agonist which involves providing a host cell expressing a polypeptide comprising a nuclear receptor ligand binding domain (such as estrogen receptor ligand binding domain) and a polypeptide comprising a coactivator or fragment thereof (TIF2 fragment in the example), administering a candidate agonist to the cell and determining whether the candidate agonist enhances binding of the coactivator or coactivator fragment to the nuclear receptor ligand binding domain (column 22). This reference teaches the use of a two-hybrid assay in the method (column 23). Chambon et al teach the use of TIF2 fragments in the method which comprise the LXXLL motif, which is taught as being necessary for binding to the nuclear receptor ligand binding domain (for example, column 34). The reference teaches that TIF2 and the cytoplasmic fragment thereof bind in an agonist-dependent manner to all nuclear receptors analyzed, including estrogen (oestrogen) receptor (column 22).

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning missing attachments or other minor formalities of this communication should be directed to the patent analyst, Zeta Adams, whose telephone number is (703) 305-3291.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

June 17, 2002